Amendments to the Specification

Please replace the paragraph beginning at line 13 of page 19 as follows:

The most distal electrode on the composite subcutaneous electrode is a coil electrode 27 that is used for delivering the high voltage cardioversion/ defibrillation energy across the heart. The coil cardioversion/defibrillation electrode is about 5-10 cm in length. Proximal to the coil electrode are two sense electrodes, a first sense electrode 25 is located proximally to the coil electrode and a second sense electrode 23 is located proximally to the first sense electrode. The sense electrodes are spaced far enough apart to be able to have good QRS detection. This spacing can range from 1 to 10 cm with 4 cm being presently preferred. The electrodes may or may not be circumferential with the preferred embodiment. Having the electrodes non-circumferential and positioned outward, toward the skin surface, is a means to minimize muscle artifact and enhance QRS signal quality. The sensing electrodes are electrically isolated from the cardioversion/defibrillation electrode via insulating areas 29. Similar types of cardioversion/defibrillation electrodes are currently commercially available in a transvenous configuration. For example, U.S. Patent No. 5,534,022, the entire disclosure of which is herein incorporated by reference, ~~disclosures~~ discloses a composite electrode with a coil cardioversion/defibrillation electrode and sense electrodes. Modifications to this arrangement [[is]] are contemplated within the scope of the invention. One such modification is illustrated in FIG. 2 where the two sensing electrodes 25 and 23 are non-circumferential sensing electrodes and one is located at the distal end, the other is located proximal thereto with the coil electrode located in between the two sensing electrodes. In this embodiment the sense electrodes are spaced about 6 to about 12 cm apart depending on the length of the coil electrode used. FIG. 3 illustrates yet a further embodiment where the two sensing electrodes are located at the distal end to the composite electrode with the coil electrode located proximally thereto. Other possibilities exist and are contemplated within the present invention. For example, having only one sensing electrode, either proximal or distal to the coil cardioversion/

defibrillation electrode with the coil serving as both a sensing electrode and a cardioversion/defibrillation electrode.

Please replace the paragraph beginning at line 1 of page 26 as follows:

FIG. 7 schematically illustrates the method for implanting the S-ICD of the present invention. An incision 31 is made in the left anterior axillary line approximately at the level of the cardiac apex. This incision location is distinct from that chosen for S-ICD placement and is selected specifically to allow both canister location more medially in the left inframammary crease and lead positioning more posteriorly via the introducer set (described below) around to the left posterior axillary line lateral to the left scapula. That said, the incision can be anywhere on the thorax deemed reasonably by the implanting physician although in the preferred embodiment, the S-ICD of the present invention will be applied in this region. A subcutaneous pathway 33 is then created medially to the ~~inframmary~~ inframammary crease for the canister and posteriorly to the left posterior axillary line lateral to the left scapula for the lead.

Please replace the paragraph beginning at line 17 of page 26 as follows:

The S-ICD canister 11 is then placed subcutaneously at the location of the incision or medially at the subcutaneous region at the left ~~inframmary~~ inframammary crease. The subcutaneous electrode 13 is placed with a specially designed curved introducer set 40 (see FIG. 8). The introducer set comprises a curved trocar 42 and a stiff curved peel away sheath 44. The peel away sheath is curved to allow for placement around the rib cage of the patient in the subcutaneous space created by the trocar. The sheath has to be stiff enough to allow for the placement of the electrodes without the sheath collapsing or bending. Preferably the sheath is made out of a biocompatible plastic material and is perforated along its axial length to allow for it to split apart into two sections. The trocar has a proximal handle 41 and a curved shaft 43. The distal

end 45 of the trocar is tapered to allow for dissection of a subcutaneous path 33 in the patient. Preferably, the trocar is cannulated having a central Lumen 46 and terminating in an opening 48 at the distal end. Local anesthetic such as lidocaine can be delivered, if necessary, through the lumen or through a curved and elongated needle designed to anesthetize the path to be used for trocar insertion should general anesthesia not be employed. The curved peel away sheath 44 has a proximal pull tab 49 for breaking the sheath into two halves along its axial shaft 47. The sheath is placed over a guidewire inserted through the trocar after the subcutaneous path has been created. The subcutaneous pathway is then developed until it terminates subcutaneously at a location that, if a straight line were drawn from the canister location to the path termination point the line would intersect a substantial portion of the left ventricular mass of the patient. The guidewire is then removed leaving the peel away sheath. The subcutaneous lead system is then inserted through the sheath until it is in the proper location. Once the subcutaneous lead system is in the proper location, the sheath is split in half using the pull tab 49 and removed. If more than one subcutaneous electrode is being used, a new curved peel away sheath can be used for each subcutaneous electrode.

Please replace the paragraph beginning at line 9 of page 28 as follows:

The S-ICD will have prophylactic use in adults where chronic transvenous/epicardial ICD lead systems pose excessive risk or have already resulted in difficulty, such as sepsis or lead fractures. It is also contemplated that a major use of the S-ICD system of the present invention will be for prophylactic use in children who are at risk for having fatal arrhythmias, where chronic transvenous lead systems pose significant management problems. Additionally, with the use of standard transvenous ICDs in children, problems develop during patient growth in that the lead system does not accommodate the growth. FIG. 9 illustrates the placement of the S-ICD subcutaneous lead system such that he problem that growth presents to the lead system is overcome. The distal end of

the subcutaneous electrode is placed in the same location as described above providing a good location for the coil cardioversion/defibrillation electrode 27 and the sensing electrodes 23 and 25. The insulated lead 21, however is no longer placed ~~in a taught~~ in a taut configuration. Instead, the lead is serpiginously placed with a specially designed introducer trocar and sheath such that it has numerous waves or bends. As the child grows, the waves or bends will straighten out lengthening the lead system while maintaining proper electrode placement. Although it is expected that fibrous scarring especially around the defibrillation coil will help anchor it into position to maintain its posterior position during growth, a lead system with a distal tine or screw electrode anchoring system 52 can also be incorporated into the distal tip of the lead to facilitate lead stability (see FIG. 1). Other anchoring systems can also be used such as hooks, sutures, or the like.

Please replace the paragraph beginning at line 12 of page 35 as follows:

The two cardioversion/defibrillation electrodes on the housing are used for delivering the high voltage cardioversion/defibrillation energy across the heart. In the preferred embodiment, the cardioversion/defibrillation electrodes are coil electrodes, however, other cardioversion/defibrillation electrodes could be used such as having electrically isolated active surfaces or platinum alloy electrodes. The coil cardioversion/defibrillation electrodes are about 5-10 cm in length. Located on the housing between the two cardioversion/defibrillation electrodes are two sense electrodes 1425 and 1427. The sense electrodes are spaced far enough apart to be able to have good QRS detection. This spacing can range from 1 to 10 cm with 4 cm being presently preferred. The electrodes may or may not be circumferential with the preferred embodiment. Having the electrodes non-circumferential and positioned outward, toward the skin surface, is a means to minimize muscle artifact and enhance QRS signal quality. The sensing electrodes are electrically isolated from the cardioversion/defibrillation electrode via insulating areas 1423. Analogous types of cardioversion/defibrillation electrodes

are currently commercially available in a transvenous configuration. For example, U.S. Patent No. 5,534,022, the entire disclosure of which is herein incorporated by reference, discloses a composite electrode with a coil cardioversion/defibrillation electrode and sense electrodes. Modifications to this arrangement [[is]] _are_ contemplated within the scope of the invention. One such modification is to have the sense electrodes at the two ends of the housing and have the cardioversion/defibrillation electrodes located in between the sense electrodes. Another modification is to have three or more sense electrodes spaced throughout the housing and allow for the selection of the two best sensing electrodes. If three or more sensing electrodes are used, then the ability to change which electrodes are used for sensing would be a programmable feature of the US-ICD to adapt to changes in the patient physiology and size over time. The programming could be done via the use of physical switches on the canister, or as presently preferred, via the use of a programming wand or via a wireless connection to program the circuitry within the canister.

Please replace the paragraph beginning at line 3 of page 40 as follows:

The core member of the different sized and shaped US-ICD will all be the same size and shape. That way, during an implantation ~~procedures~~ procedure, multiple sized US-ICDs can be available for implantation, each one without a core member. Once the implantation procedure is being performed, then the correct sized US-ICD can be selected and the core member can be inserted into the US-ICD and then programmed as described above. Another advantage of this configuration is when the battery within the core member needs replacing it can be done without removing the entire US-ICD.

Please replace the paragraph beginning at line 13 of page 40 as follows:

Figures 19-26 refer generally to alternative S-ICD/US-ICD canister embodiments. Although the following canister designs, various material

constructions, dimensions and curvatures, discussed in detail below, may be incorporated into either S-ICD or US-ICD canister ~~embodimens~~ embodiments, hereinafter, these attributes will be discussed solely with respect to S-ICDs.

Please replace the paragraph beginning at line 21 of page 45 as follows:

Compliant canister housings 192 often provide increased comfort when implanted in patient recipients. S-ICD canisters 190 formed from such materials permit limited, but significant, deflection of the canister housing 192 with certain thoracic motions. Examples of permitted deflections are ones that are applied to the canister housing 192 by surrounding muscle tissue. The use of a compliant canister housing is particularly beneficial in canister housing embodiments that extend over a significant portion of a patient's thorax. The compliant material in these ~~embodiment~~ embodiments may comprise a portion of the canister housing, or alternatively, may comprise the canister housing in its entirety. The correct material selection (or combination thereof), therefore, is helpful in eliminating patient awareness of the device and in improving the long-term wearability of the implanted device.

Please replace the paragraph beginning at line 15 of page 75 as follows:

Turning now to Figure 23A, a S-ICD canister 220 having a duckbill-shaped canister housing 222 is shown. The duckbill-shaped canister housing 222 has a proximal end 226 and a distal end 234. The proximal end 226 of the duckbill-shaped canister housing 222 further includes a main housing member 228 and a distal housing member 230. The distal housing member 230 is an elongated segment extending distally from the distal end of the main housing member 228. Although the two segments differ in their size and shape, the distal housing member 230 and main housing member 228 are generally contiguously and fluidly attached to one another and may be formed from a single mold. In alternative embodiments, however, the distal housing member 230 may be hinged

to the main housing member 228. The distal housing member 230 also generally comprises a material that is similar in composition to that forming the main housing member 228. In alternate embodiments, however, the distal housing member 230 may include a material that ~~possess~~ possesses enhanced electrically insulated characteristics.